



Name and Clinic Number

Approval Date: June 21, 2018
Not to be used after: November 9, 2018

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Cochlear Promontory Stimulation for Treatment of Tinnitus: Towards Developing an Implantable Device

IRB#: 17-004832

Principal Investigator: Matthew L. Carlson, M.D. and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.



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CONTACT INFORMATION

You can contact ...	At ...	If you have questions about ...
Principal Investigator(s): Matthew L. Carlson, M.D. Study Team Contact: Charles L. Anzalone	Phone: (507) 284-8532 Phone: (507) 284-8532 Institution Name and Address: Mayo Clinic 200 1 st St SW Rochester, MN 55905	<ul style="list-style-type: none">Study tests and proceduresResearch-related injuries or emergenciesAny research-related concerns or complaintsWithdrawing from the research studyMaterials you receiveResearch-related appointments
Mayo Clinic Institutional Review Board (IRB)	Phone: (507) 266-4000 Toll-Free: (866) 273-4681	<ul style="list-style-type: none">Rights of a research participant
Research Subject Advocate (The RSA is independent of the Study Team)	Phone: (507) 266-9372 Toll-Free: (866) 273-4681 E-mail: researchsubjectadvocate@mayo.edu	<ul style="list-style-type: none">Rights of a research participantAny research-related concerns or complaintsUse of your Protected Health InformationStopping your authorization to use your Protected Health Information
Research Billing	Rochester, MN: (507) 266-5670	<ul style="list-style-type: none">Billing or insurance related to this research study



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1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have been diagnosed with tinnitus.

The plan is to have about 30 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

The purpose of this study is to look at the safety and efficacy of cochlear promontory stimulation in the short term relief of tinnitus. The secondary goal of the study is to determine the optimum region(s) of the cochlear promontory in planning for an implantable electrical device for long term tinnitus suppression.

3. Information you should know

Who is Funding the Study?

The Department of Otorhinolaryngology – Head and Neck Surgery, Mayo Clinic, Rochester, MN is funding this study.

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

4. How long will you be in this research study?

You will be in the study for approximately 4 months.



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5. What will happen to you while you are in this research study?

The Screening Visit will take about 30 minutes. During this visit, we will do some tests and procedures to see if you are eligible to take part in this research study.

At this visit we will:

- Ask you about your medical history, social history and current medications
- Perform a physical exam, including an ear, nose and throat examination
- Give you some questionnaires to fill out about [your general health and well-being, quality of life, mental health, emotional health, mood, and tinnitus history].

You will need to have the following exams, tests or procedures for this study: Audiogram and immittance testing, distortion product otoacoustic emission testing, auditory brainstem response, tinnitus pitch, level matching, masking levels and residual inhibition testing, CT temporal bone, and MRI head with / without contrast.

1. The audiogram and immittance testing is a basic hearing test.
2. The distortion product otoacoustic emission testing is to understand the function of the inner ear. A soft insert is placed in the ear canal and the inner ear's response to sound is measured.
3. Auditory brainstem response measures the pathway of sound and its interpretation by the brain. Monitors (sticky pads) are placed on the scalp and responses to sound are measured.
4. Tinnitus pitch, level matching, masking levels and residual inhibition are performed to better understand your tinnitus. Sounds are introduced into the ear to help the patient define their tinnitus, by determining the pitch and loudness of their tinnitus and how long (if at all) their tinnitus stops with sound.
5. CT temporal bone scan is a "CAT" scan to look at the bones of the ear.
6. MRI with / without contrast is used to evaluate the soft tissues / nerves around the ear. With / without contrast are used to better visualize structures on radiographic imaging.

If you have had some of these exams, tests, or procedures recently, they may not need to be repeated. This will be up to the Principal Investigator.

The Principal Investigator will review the results of these tests and procedures. If you aren't eligible, the Principal Investigator will tell you why.

If you are eligible to be in the study, you will be asked to participate in the following: cochlear promontory stimulation. This involves topically anesthetizing the ear drum and then placing a small probe through the drum into the middle ear. A series of electrical stimulation tests will be performed for relief of tinnitus.



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During this study, we will ask you to fill out questionnaires about your tinnitus (Tinnitus Handicap Inventory, Tinnitus History Questionnaire, Tinnitus Functional Index, Visual Analog Scale), mental health (Generalized Anxiety and Depression Score (GAD7), Health Anxiety Inventory (HAI-s), Patient History Questionnaire (PHQ8)), and your personality (NEO – Personality Inventory). We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The questionnaires will take about 2-3 hours to complete.

If you take part in this research, you will be responsible to be present for the required schedule of testing and fill out the questionnaires as accurately and fully as possible.

Table 1: Schedule of Events

Assessment	Screening and Baseline, Enrollment	F/U Questionnaires (3 separate baselines in wk prior to eval)	Visit 1	Visit 2 (1 week after)	Visit 3 (1 week after)	Final Visit (3 mo after last treatment)
Informed Consent Form	X					
Demographics	X					
Diagnosis of Tinnitus	X		X	X	X	X
Medical and Social History	X					
Physical Exam	X		X	X	X	X
Current Medications	X		X	X	X	X
THI, TFI, VAS,	X	XXX	X	X	X	X
GAD7, PHQ, sHAI, THQ, NEO PI	X					
Adverse Events	X					
Temporal Bone CT			X			
Contrast Head MRI			X			
Audiogram with immittance testing			X	X	X	X
Pitch and level matching of tinnitus			X	X	X	X
DPOAE			X	X	X	X
ABR			X			
Promontory Stimulation			X	X	X	



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6. What are the possible risks or discomforts from being in this research study?

Cochlear promontory stimulation has been well studied in patients being tested for cochlear implants. It has also been studied safely in patients with tinnitus. There is a risk of persistent tympanic membrane perforation (hole in the ear drum). This may not cause any problems to the patient; however, complications sometimes occur such as hearing loss and infection in the middle ear. A small procedure to repair a perforated eardrum is an option if it does not heal by itself. The risk of electrical current spread on the surface of the bone of the inner ear could possibly cause facial nerve stimulation (resulting in movement of the face), pain, or if strong enough, sensorineural hearing loss. The risks of these occurring are low.

There is no radiation associated with MRI, but people who have metal devices like pacemakers cannot have an MRI and will not be able to participate in the study. Some people with claustrophobia may feel too closed in and may not tolerate MRI scanning. If you feel too confined in the MRI scanner you can inform the technologist and the MRI scan will be stopped. The MRI machine makes loud knocking sounds when it is scanning. Because of this you will be asked to wear earplugs while getting your MRI scan. The earplugs minimize discomfort from noise and keep the MRI noise within the safety range.

The contrast agent you will receive is FDA-approved and used routinely for MRI exams. It contains a material called gadolinium, a rare metal. About 1 in 100 people may notice discomfort, tingling or warmth in the lips, metallic taste in the mouth, tingling in the arm, nausea, or headache. These side effects usually last only for a short time and go away as your body adjusts to the gadolinium. There is a small risk of an allergic reaction to gadolinium. However, a severe allergic reaction occurs in less than one in 300,000 people. The needle placed in your vein to give you the gadolinium may cause minor pain, bruising and/or infection at the injection site. Studies have shown that small amounts of gadolinium may remain in the body of patients who have received these injections. The effect of this, if anything, is unknown at this time.

You will be exposed to radiation from the Computed Tomography scan of the head. For the amount of radiation has a low risk of harmful effects.

Audiogram and immittance testing is a hearing test with minimal to no risk.

Tinnitus pitch, level tinnitus pitch, level matching, masking levels and residual inhibition testing is performed to better define your tinnitus and is associated with minimal to no risk.

Auditory brainstem response is a neurologic test of auditory brainstem function in response to auditory stimuli. The test is associated with minimal to no risk.



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Distortion product otoacoustic emissions are used to determine cochlear hair cell function. There is minimal to no risk associated with this procedure.

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7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If during the pilot study the placement or use of the cochlear promontory stimulation electrode is documented or suspected by the surgeon to cause sensorineural hearing loss or undue discomfort.
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.



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Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

9. What are the possible benefits from being in this research study?

This study is evaluating short term relief of tinnitus. The information learned may aid in the development of a future implantable device capable of providing long term tinnitus relief for those who suffer from chronic tinnitus.

Others with chronic tinnitus may benefit in the future from what we learn in this research study.

10. What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. Your other choices may include tinnitus masking, cognitive behavioral therapy, or other alternative treatments. Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

11. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Temporal bone CT, Auditory brainstem response, tinnitus pitch, level matching, masking levels and residual inhibition testing

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of standard clinical care. These tests and procedures are:

- Head MRI, distortion product otoacoustic emissions, audiogram and immittance testing

You will also be responsible for any co-payments and deductibles.



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12. Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

13. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Data extracted from the cochlear promontory stimulation monitoring system will be collected by the investigator. The data will then be extracted to a secure database on the Mayo Clinic server. Once the data has been transferred, the data will be deleted from the flash drive. Only the principal and co-investigators will have access to this data. Visit data will also be entered into this secure database. Access to the database will be restricted to research staff and will be unavailable to any other third party.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.



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With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.



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Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

	/	/	:	AM/PM
Printed Name	Date		Time	

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/	/	:	AM/PM
Printed Name	Date		Time	

Signature